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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,411	03/12/2007	Robert Blumenthal	59526(47992)	1153
21874 7590 01/05/2011 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
WANG, SHENGJUN				
ART UNIT		PAPER NUMBER		
1627				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,411

Applicant(s)

BLUMENTHAL ET AL.

Examiner

Shengjun Wang

Art Unit

1627

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5,19-22 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-18,23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Receipt of applicants' amendments and remarks submitted November 20, 2010 is acknowledged.

Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 6-18, 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maciazek et al. in view of Gander (US 4,323,581).
4. Maciazek et al. teaches that Retinoid-induced repression of HIV core promoter activity inhibits virus replication. Retinoid particularly inhibit the infection of cells. Further it is known that the rate of mother to child transmission of HIV-1, progression to AIDS from HIV-1 infection, and AIDS-associated mortality are all inversely correlated with serum vitamin A levels. Maciazek particularly teaches that retinol or its metabolite repress HIV-1 replication. See, particularly, the abstract, pages 5863-5866.
5. Maciazek et al. do not teach expressly the employment of 4-HPR for treating HIV infection or for inhibiting HIV infection to cells.
6. However, Gander et al. teaches that 4-HPR is a retinoid derivative, with the function of retinoids, but with low systemic toxicity. See, particularly, col. 1, line 38 to col. 2, line 53.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use 4-HPR as a retinoid for treating HIV infection or for inhibiting HIV infection of cells.

A person of ordinary skill in the art would have been motivated to use 4-HPR as a retinoid for treating HIV infection or for inhibiting HIV infection of cells because 4-HPR is a known retinoids derivative with low systemic toxicity. As to the functional limitations “inhibiting a viral attachment/entry or exit phase of a virus” recited in claim 23, note, the recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Further, the instant claims are directed to affecting a biochemical pathway with old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (inhibiting HIV infection in cell) for the compounds, e.g., retinoid compounds, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant’s attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various

biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Furthermore, the further employment of other known anti-HIV agents for the treatment of HIV infection would have been obvious to one of ordinary skill in the art, as it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known anti-HIV agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Finally, the optimization of a result effective parameter, e.g., effective amount of a therapeutic agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Arguments

7. Applicants' amendments and remarks submitted November 10, 2010 have been fully considered. The amendments and remarks are persuasive with regard to the rejections under 35 U.S.C. 112, However, are not persuasive for the rejections set forth above.

Applicants contend that the cited reference does not teach or suggest all the elements, particularly, the alleged function of the retinoids, such as "ceramide-generating retinoid" and "an inhibitor of at least one enzyme essentially to ceramide metabolism." The arguments are untenable. The claims read on a method comprising administering the retinoid compound to patients infected with a virus, such as HIV. The cited references have fair suggest such method. As to the particular biological mechanism of the therapeutic method, note, the fact that applicant

has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further, as discussed in the rejections, "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In addition, "[i]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In *re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990); see also *Perricone*, 432 F.3d at 1377-78 (noting that the realization of a new benefit of an old process does not render that process patentable); *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (stating in the context of a claimed process that was drawn to the same use comprising the same steps of the prior art, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

8. Applicants also argue that Gander reference only teach that 4-HPR has anti-cancer activities as does retinoic acid, and does not teach that 4-HPR is functionally equivalent to retinoic acid for all purpose. The arguments are not persuasive. Gander et al. discloses that retinoids (not be limited to retinoic acid) play an essential role in controlling the **normal** differentiation of epithelial tissue. (col. 1, lines 38-40, emphasis added). Gander teaches that 4-HPR retains the active as retinoids but with much less toxicity. Therefore, one of ordinary skill in the art would have been motivated to try 4-HPR as a substitute of other known retinoid because of its known low toxicity.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627

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